NOV 6 2012

510(k) Summary Pursuant to 21 CFR 807.92

Date of preparation: November 5, 2012

1. Submitted By: Insurgical, LLC
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   Austin, Texas 78759

2. Contact: David C. Furr
   FDC Services, LLC
   8708 Capehart Cove
   Austin, Texas 78733
   512-906-9654

3. Product: Insurgical™ Single Use Power Equipment
   Unclassified
   Product Code: KIJ

4. Common/Trade Name:

   Instrument, Surgical, Orthopedic, DC Powered Motor and Accessory/Attachment

   Insurgical™ Single Use Power Equipment

Description:

The Insurgical™ Single Use Power Equipment System includes surgical power tools and rechargeable batteries. The battery powered DC Motor products include the Insurgical Drill, and the Insurgical Orthopedic Reamer.

Insurgical handpieces and attachments are provided pre-sterilized and ready to use. The powered DC Motor products and attachments are single-use and intended to be disposed of after use. The batteries can be recharged and are re-usable. The Insurgical Drill is designed for drilling holes and placing bone screws in a variety of reconstructive and trauma procedures. The Insurgical Orthopedic Reamer can be used for boring, drilling, and reaming during orthopedic procedures.

Intended Use:

Insurgical ™ Single Use Power Equipment is intended for use in the cutting, drilling, decorticating, and smoothing of bone and other bone related tissue in a variety of surgical procedures. It is also usable in the placement or cutting of screws, wires, pins, and other fixation devices. It can also be used to cut metal.

Testing and Technological Characteristics:

The Insurgical™ Single Use Power Equipment System includes DC powered components with accessories. The devices are hand-held and provided sterile. They are for single use orthopedic surgical applications.

The handpieces include a trigger lock, which can be engaged to safely allow for attachment of accessories. The devices are powered by DC batteries, which are non-sterile and reusable.

The following testing was conducted with successful outcome to establish device safety and equivalence:

- IEC 60601-1-2 Medical Electrical Equipment/Part 1: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility
- CISPR 11 Industrial, scientific and medical (ISM) radio frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement
- IEC 61000-4-2 Electromagnetic Compatibility Part 4: Testing and Measurement Techniques Section 2: Electrostatic Discharge Immunity Test
- IEC 61000-4-3 Electromagnetic Compatibility for Electrical and Electronic Equipment, Part 3: Immunity to Radiated, Radio Frequency, Electromagnetic Fields
- Cadaveric simulated use test
- Laboratory validation of aseptic battery transfer process
- UL1642 Safety for Lithium Batteries
- ISO 10993-5 Cytotoxicity

Substantial Equivalence:

The Insurgical Single Use Power Equipment is substantially equivalent to Stryker System 4000 Heavy Duty Battery Powered Equipment (K972367).

The predicate device has similar technical features, indications for use, and the safety and effectiveness of the devices is equivalent.

Conclusions:

The predicate device and the Insurgical Single Use Power Equipment share similar indications, technology, and application. The Insurgical product is equivalent to the predicate device products in key areas of performance that affect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

Insurgical, LLC
% FDC Services, LLC
Mr. David C. Furr
Principal Consultant
8708 Capehart Cove
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November 6, 2012

Re: K112599
Trade/Device Name: Insurgical™ Single Use Power Equipment
Regulatory Class: Unclassified
Product Code: KIJ
Dated: October 03, 2012
Received: October 10, 2012

Dear Mr. Furr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K112599

Device Name: Insurgical™ Single Use Power Equipment

Indications for Use:

Insurgical™ Single Use Power Equipment is intended for use in the cutting, drilling, decorticating, and smoothing of bone and other bone related tissue in a variety of surgical procedures. It is also usable in the placement or cutting of screws, wires, pins, and other fixation devices. It can also be used to cut metal.

Prescription Use__X__ or Over-the-counter use
(per CFR 801.109)

Concurrence of CDRH

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112599